AWARD NUMBER: W81XWH-14-1-0533

TITLE: Bench to Bedside: Understanding Symptom Response to Acupuncture Treatment and Designing a Successful Acupuncture Treatment Program

PRINCIPAL INVESTIGATOR: Dr. Lisa Conboy

CONTRACTING ORGANIZATION: New England School of Acupuncture
Newton, MA 02458

REPORT DATE: October 2015

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
October 2015	Annual	30 Sept 2014 –28 Sept 2015

4. TITLE AND SUBTITLE
Bench to Bedside: Understanding Symptom Response to

Acupuncture Treatment and Designing a Successful Acupuncture

Treatment Program

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-14-1-0533

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Lisa Conboy

E-Mail:lisa_conboy@hms.harvard.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
New England School of Acupuncture
150 California St. 3rd Floor
Newton, MA 02458

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

In 2009, our study team was awarded a three-year Congressionally Directed Medical Research Program grant to implement the RCT "The Effectiveness of Acupuncture in the Treatment of Gulf War Illness" (W81 XWH). We successfully completed this project in January of 2013 with positive results to report. This current application has two objectives utilizing data from the parent grant: 1) Better define and describe this complex disease and how healing may happen using acupuncture, 2) Report on the best acupuncture protocols for GWI veterans and specific GWI presentations. Aim 2 has been completed this year as was planned in the statement of work. Three abstracts to the scientific conference of The Society for Acupuncture Research were accepted for presentation and publication: 1) How TCM Practitioners Treat Gulf War Illness; findings of an RCT with individualized treatments, 2) A Case Study of Gulf War Illness in a Woman, 3) Improvements in Perceived Social Support and Health Behaviors following Acupuncture Treatment in a Veteran Population. Year 2 will see these abstracts developed into manuscripts along with the development of other ideas as informed by our expert consultants.

15. SUBJECT TERMS
Gulf War Illness, Complex Medical Illness, Acupuncture, Treatment Trial, Secondary Date Analysis

16. SECURITY CLASSIFICATION OF:
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a. REPORT	b. ABSTRACT	c. THIS PAGE	17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	11	19b. TELEPHONE NUMBER *(include area code)*

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

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1. INTRODUCTION:

This project is a secondary data analysis and program evaluation of the Congressionally Directed Medical Research Program funded project "The Effectiveness of Acupuncture in the Treatment of Gulf War Illness" (W81 XWH). <u>Objectives:</u> This application has two objectives to complete using data from the parent grant: 1) Better define and describe this complex disease and how healing may happen using acupuncture, 2) Report on the best acupuncture protocols for GWI veterans and specific GWI presentations

2. KEYWORDS: Gulf War Illness, Complex Medical Illness, Acupuncture, Treatment Trial, Secondary Data Analysis

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Following the directives of the "Recommendation for Funding" letter of April 11, 2014, two Specific Aims from the original application are supported: **<u>Aim 2:</u> Complete scale construction for remaining psychosocial and clinical measures, <u>Aim 3:</u> Determine the relationships between dose of acupuncture and effect on secondary outcomes in this sample.** Aim 2 has been completed this year as was planned in the statement of work.

What was accomplished under these goals?

The IRB review and HRPO/ACURO approval was competed by month 2.

As planned we completed by month 2 the training of the research assistant, and review of goals with consultants. Once funding was achieved the team commenced with regular meetings (approximately every 6 weeks) to review program goals and then begin the process of discussing which relevant variables we want to explore, what abstracts we want to produce and manuscripts we will work toward. Follow-up group e-mails will solidify our process.

Data cleaning and relevant variable identification were completed by Dr Conboy and the Research Assistant (Kai Yin Hsu) by month 8.

We are currently (in month 12) exploring the relationship between study variables and outcome. This process is scheduled to continue through month 19.
Our initial assessment of variables includes descriptive analyses including simple pair-wise Pearson correlations among our variables. For each type of correlation, both cross-sectional and longitudinal data will be evaluated. Cross-sectional data will be evaluated using only baseline measurements and using the mean of each measure for each participant. Longitudinal associations will be evaluated by correlating participant-specific slope estimates for each measure.

What opportunities for training and professional development has the project provided?

Not Applicable/Nothing to Report.

How were the results disseminated to communities of interest?

Three abstracts are accepted for presentation to the Society for Acupuncture Research's annual conference in Boston, MA. This conference is a meeting place for practitioners and researchers from the general community as well as the Department of Veterans Affairs.

What do you plan to do during the next reporting period to accomplish the goals?

Three abstracts from the project will be presented and published in the proceedings of the Society for Acupuncture Research. These abstracts are provided in the Appendices. We will continue with these projects to produce manuscripts.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to Report

What was the impact on other disciplines?

Nothing to Report

What was the impact on technology transfer?

The results of this project will allow for a smooth implementation of an acupuncture treatment program for veterans, active military personnel, and the general citizen. This information will be most easily applied by, and results will be supplied to, the Department of Veterans Affairs.

What was the impact on society beyond science and technology?

Our results have the potential to inform medical decision making in support of acupuncture as a viable treatment for veterans with GWI.

5. CHANGES/PROBLEMS

Nothing to Report

6. PRODUCTS:

Publications, conference papers, and presentations

Nothing to Report

Journal publications

Nothing to Report

Books or other non-periodical, one-time publications.

Nothing to Report

Other publications, conference papers, and presentations.

Three abstracts were accepted for publication to the Society for Acupuncture Research's Annual Conference Nov 11th-13, 2015. The abstracts are listed in the Appendix and resulting manuscripts are in preparation. The projects are:

1. How TCM Practitioners Treat Gulf War Illness; findings of an RCT with individualized treatments

2. Improvements in Perceived Social Support and Health Behaviors following Acupuncture Treatment in a Veteran Population

3. A Case Study of Gulf War Illness in a Woman

Website(s) or other Internet site(s)

Nothing to Report

Technologies or techniques

Nothing to Report

Inventions, patent applications, and/or licenses

Nothing to Report

Other Products

Nothing to Report

7.   PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Lisa Conboy
Project Role:	Principal Investigator
Researcher Identifier:	ORCID # 0000-0003-2218-7841
Nearest person month worked:	5

Contribution to Project: Dr. Lisa Conboy has acted as the Principal Investigator on this project. She is the main statistician, completing data cleaning and scale construction of the biomedical survey data. Dr. Conboy has conducted regular meeting with consultants, co-investigator and research assistants on the project.
Funding Support: N/A

Name:	Meredith St. John
Project Role:	Treatment Specialist
Researcher Identifier:	N/A
Nearest person month worked:	1

Contribution to Project: Meredith St. John has acted as Treatment Specialist for this project. She has reviewed acupuncture specific data from research assistant and consultants.
Funding Support: N/A

Name:	Kai-Yin Hsu

Project Role: Research Assistant
Researcher Identifier: ORCID # 0000-0002-5062-9953
Nearest person month worked: 6

Contribution to Project: Kai-Yin Hsu is the Research Assistant for this project. She has coded and organized acupuncture specific data. She has participated in regular meetings with her PI and consultants.
Funding Support: N/A

Name: Dr. Joseph Locascio
Project Role: Biostatistician
Researcher Identifier: N/A
Nearest person month worked: 1

Contribution to Project: Dr. Joseph Locascio is the Biostatistician for the project. He has provided statistical consultation and analysis for the project.
Funding Support: N/A

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to Report

What other organizations were involved as partners?

Nothing to Report

8.   SPECIAL REPORTING REQUIREMENTS

Not Applicable

9.   APPENDICES

Three abstracts accepted for publication to the Society for Acupuncture Research's Annual Meeting.

How TCM Practitioners Treat Gulf War Illness; findings of an RCT with individualized treatments.

Joe Chang LicAc, Lisa Taylor-Swanson Lic Ac, Rosa Schnyer DAOM, Lisa Conboy MA MS ScD.

Purpose:
This project describes the presentations and treatment of Gulf War Illness (GWI) from a TCM point of view using various retrospective analysis techniques. Parent data comes from a completed 3.5-year Army-funded RCT "The Effectiveness of Acupuncture in the Treatment of GWI". Individualized acupuncture treatments were administered by practitioners in the community for a possible treatment window of 6 months. A standardized treatment protocol was not used; instead experienced practitioners were given training in the known medical information of GWI, and encouraged to treat with discretion while keeping detailed treatment records. We found positive results using our biomedical outcome measurements and now turn to better understand what took place during the individual diagnosis and treatment plans. Our naturalistic data, is heterogeneous and complex representing the work of 32 practitioners treating the range of GWI presentations in the best manner they know, with only limited restriction (e.g. herbs were not allowed).

Methods: First, to better understand how patient presentations change over time, we map (using a sample of patients) each symptom using Matrix Analysis to visually explore the relationships between symptoms and diagnoses offered at baseline with those gathered over the course of treatment. Second, we use cluster analysis to empirically look for linkages between factors presented at baseline (signs, symptoms, diagnosis) to begin to articulate how to talk about GWI in terms of TCM. Our eventual project goal is to add treatment data and develop a TCM model (or models) for GWI.

Results: We are currently implementing these descriptive analyses.

Conclusion: GWI is not a recognized TCM diagnosis but the novelty of our emergent treatment data may offer new answers to difficult treatment questions. We are consolidating our clinical data into a form that practitioners can use to improve the health of GWI veterans and others with similar complex illnesses.

A Case Study of Gulf War Illness in a Woman

Lisa Taylor-Swanson Lic Ac, Lisa Conboy MA MS ScD.

Background Gulf War Illness (GWI) is a complex illness with multiple symptoms, including fatigue, sleep and mood disturbances, cognitive dysfunction and musculoskeletal pain. Symptoms are often severe in intensity and interfere with activities of daily life. People with GWI experience comorbid medical diagnoses, including chronic fatigue syndrome, fibromyalgia, irritable bowel syndrome, arthralgia, depression, and anxiety disorders. GWI has not been found to create a unique syndrome by sex (Shapiro, Lasarev, & McCauley, 2002); however, there is evidence of differential endocrine change by sex (Craddock et al., 2014). Little research has evaluated women's experiences of GWI; therefore, the purpose of this study is to evaluate one woman's symptoms and change over time during the course of receiving bi-weekly acupuncture care.

Methods One female participant's chart notes were randomly selected. Thematic content analysis was employed to determine themes in symptoms and change over the course of 17 acupuncture treatments.

Results This woman experienced at the first office call: back pain (main complaint), abdominal pain, depression, anxiety, temperature dysregulation, poor sleep, irregular menses, thirst, headache, fatigue, recurrent urinary tract infections, restless leg syndrome and floaters in her vision. Her differential diagnosis was KD Qi deficiency and LIV Qi stagnation. Over the course of treatment, her back pain was decreased and sleep, mood, memory and concentration improved. However, she had not had a menstrual period in seven months. Her differential diagnosis was relatively stable over the course of treatment, except the addition of HT, LIV and KD Yin deficiency, and LIV Yang rising.

Conclusions Multiple systems are affected by GWI and biweekly treatment with acupuncture decreased several symptoms in this case. However, persistent endocrine dysregulation, evidenced by amenorrhea, indicates that ongoing acupuncture care might be beneficial. Ongoing imbalances of Yin, Yang and Qi indicate the level of severity of dysregulation in GWI.

Improvements in Perceived Social Support and Health Behaviors following Acupuncture Treatment in a Veteran Population

Lisa Conboy MA MS ScD and Christine Cronin DAOM

Purpose: There is a growing body of evidence that acupuncture treatment is effective and well tolerated by a veteran population. Less is known about the stage of reintegration a time at which the service member can face social, psychological and physical challenges[1]. Social support is a known predictor of health status and correlate of health improvement. Scientific attempts to administer social support have shown at best moderate effectiveness[2]. This analysis considers if acupuncture treatment is associated with improvements in social support and healthy behaviors in a veteran sample.

Statistics of CAM use within military populations ranges from 23% to 81.5% depending on the population surveyed and the types of CAM surveyed[1–9]. Despite its varied use among veterans and military populations, 69 % of active military reported they would use CAM if it was provided in a military treatment facility (MTF) between 69%[2] and 73% to 99.5% of veterans would utilize CAM modalities it offered within the within the VA healthcare system[3,5].

A 2002 study involving CAM use in military veterans found that 49.6% (252 of the 508 subjects surveyed) reported CAM use and that were that military veterans who use/d CAM were significantly less likely to drink more than 2 alcoholic beverages/day and were less likely to be current smokers [1].

In 2013, our study team competed the Army funded project "The Effectiveness of Acupuncture in the Treatment of Gulf War Illness" (W81XWH-09-2-0064). This Phase II Randomized Controlled Trial (n=104) tested the effects of individualized acupuncture treatments offered in extant acupuncture practices. Statistically and clinically significant improvements were found after 6 months of treatment for our primary outcome analysis the SF-36 physical component scale score (SF-36P), as well as pain, and self-reported main complain. Measurement of Perceived Social Support as well as health behaviors were also recorded at baseline, 2, 4 and 6 months using validated reliable surveys.
Methods:

Results: Statistically significant (to $p<=0.05$) improvements were found in subjects perceived social support[3] post program. Interestingly these affective changes were not due to the addition of new social contacts as we found no statistically significant changes in social networks[4]. The improvements appear to be due to changes in how the individuals feel in relation to their social world. Subjects also reported decreases in alcohol and tobacco use.
Conclusion: Acupuncture treatment may help veterans engage in positive health behaviors and feel more supported in their social world, and this increased support is associated with a broad range of positive mental and physical health effects. Such changes can help with re-integration to civilian life.

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[1] Adler, A. B., Zamorski, M., & Britt, T. W. (2011). The psychology of transition: Adapting to home after deployment. In Adler, A. B., Bliese, P. D., & Castro, C. A. (eds.), Deployment psychology. Washington, DC: American Psychological Association.

[2] Saab PG, et al. ENRICHD Investigators.(2009). The impact of cognitive behavioral group training on event-free survival in patients with myocardial infarction: the ENRICHD experience. J Psychosom Res. 2009 Jul;67(1):45-56. Epub 2009 Apr 1.

[3] Cohen, S., et al (1985). <u>Measuring the functional components of social support</u>. In I. G. Sarason & B. R. Sarason (Eds.), Social support: Theory, research and application (pp. 73-94). The Hague, The Netherlands: Martinus Nijhoff.

[4] Cohen, S., et al (1997). Social ties and susceptibility to the common cold. Journal of the American Medical Association, 277, 1940-1944